

## II. AMENDMENT TO THE CLAIMS

Claim 1. (Currently Amended) An oral dosage form, comprising ~~active agents consisting essentially of an orally therapeutically effective amount of~~

(A) ~~at least one an~~ opioid agonist ~~selected from the group consisting of morphine, hydromorphone, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine and pharmaceutically acceptable salts thereof,~~

(B) acetaminophen, and

(C) ~~at least one an~~ opioid antagonist; the dosage form having a ratio of opioid antagonist to opioid agonist to acetaminophen that provides a combination product which is analgesically effective when the combination is administered orally, but which (i) is aversive in physically dependent human subjects when administered in the same amount and in a higher amount than said therapeutically effective amount; and (ii) maintains an analgesic effect but does not increase analgesic efficacy of the opioid agonist together with the acetaminophen relative to the same therapeutic amount of opioid analgesic together with the acetaminophen when administered to human patients without said opioid antagonist ~~said dosage form further comprising a sustained release carrier which causes said opioid agonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.~~

Claim 2. (Cancelled)

Claim 3. (Previously Presented) The oral dosage form of claim 1, wherein the opioid agonist is hydrocodone or a pharmaceutically acceptable salt thereof and the antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

Claims 4-7 (Cancelled)

Claim 8. (Currently Amended) The oral dosage form of claim 1, further comprising ~~one or more pharmaceutically acceptable inert excipients~~ a sustained release carrier that causes said opioid agonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

Claim 9. (Currently Amended) The oral dosage form of claim 6~~1~~, wherein said opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephene, cyclazocine, levallorphan, pharmaceutically acceptable salts thereof and mixtures thereof.

Claim 10. (Currently Amended) The oral dosage form of claim 6~~1~~, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

Claim 11. (Cancelled)

Claim 12. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is oxycodone or a pharmaceutically acceptable salt thereof.

Claim 13. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is codeine or a pharmaceutically acceptable salt thereof.

Claim 14. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is hydromorphone or a pharmaceutically acceptable salt thereof.

Claim 15. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is levorphanol or a pharmaceutically acceptable salt thereof.

Claim 16. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is meperidine or a pharmaceutically acceptable salt thereof.

Claim 17. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is methadone or a pharmaceutically acceptable salt thereof.

Claim 18. (Previously Presented) The oral dosage form of claim 1, wherein said opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof and said opioid agonist is morphine or a pharmaceutically acceptable salt thereof.

Claim 19. (Currently Amended) The oral dosage form of claim 1, wherein the sustained release carrier further causes said opioid antagonist to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

Claim 20. (Currently Amended) The oral dosage form of claim 1, wherein the sustained release carrier further causes the acetaminophen to be released over a time period of about 8 to about 24 hours when orally administered to a human patient.

Claim 21. (Original) The oral dosage form of claim 1, wherein the dose of opioid agonist would be subtherapeutic if administered without the acetaminophen.

Claim 22. (Original) The oral dosage form of claim 1, wherein the dose of acetaminophen would be subtherapeutic if administered without the opioid agonist.

Claim 23. (Original) The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 10 mg to about 2000 mg.

Claim 24. (Original) The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 25 mg to about 1000 mg.

Claim 25. (Original) The oral dosage form of claim 1, wherein the amount of acetaminophen included in the dosage form is from about 325 mg to about 1000 mg.

Claim 26. (Currently Amended) The oral dosage form of claim 1, wherein the ~~amount of~~ opioid agonist and the ~~amount of~~ acetaminophen ~~are each lower than would be required when either drug is used alone~~ would each be subtherapeutic if not used in combination with each other.

Claim 27. (Currently Amended) The oral dosage form of claim ~~4~~ 8, wherein said sustained release carrier causes said antagonist and said acetaminophen to be released over a time period of about 8 to about 24 hours when the dosage form is orally administered to a human patient.

Claim 28. (Cancelled)

Claim 29. (Currently Amended) The oral dosage form of claim ~~28~~ 1, wherein said opioid ~~antagonist~~ agonist is selected from the group consisting of ~~naltrexone, naloxone, nalmephen,~~ eyclazocine, levallorphan morphine, hydromorphone, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine, tramadol, pharmaceutically acceptable salts thereof and mixtures thereof.

Claim 30. (Currently Amended) The oral dosage form of claim 29, wherein ~~the amount of~~ acetaminophen included in the dosage form is from about 10 mg to about 2000 mg said opioid antagonist is selected from the group consisting of naltrexone, naloxone, nalmephen, cyclazocine, levallorphan, pharmaceutically acceptable salts thereof, and mixtures thereof.

Claim 31. (Currently Amended) The oral dosage form of claim ~~27~~ 29, wherein ~~the amount of either or both the opioid agonist and the acetaminophen are lower than would be required when either drug is used alone~~ would be subtherapeutic if not used in combination with each other.

Claim 32. (Previously Presented) A method of treating pain, comprising administering an oral dosage form according to claim 1 orally to a human patient in an analgesically effective amount.

Claims 33-34 (Cancelled)

Claim 35. (Currently Amended) The method of claim ~~34~~ 32, wherein ~~further comprising preparing said oral dosage form with~~ further comprises a sustained release carrier such that the dosage form is administrable on a twice-a-day or on a once-a-day basis.

Claim 36. (Currently Amended) The ~~oral dosage form~~ method of claim 32, wherein the amount of acetaminophen included in the dosage form is from about 10 mg to about 2000 mg.

Claim 37. (Currently Amended) The ~~oral dosage form of claim 1~~ method of claim 35, wherein the sustained release carrier causes said opioid agonist to be released over a time period of about 12 hours when orally administered to a human patient.

Claim 38. (Currently Amended) The ~~oral dosage form of claim 1~~ method of claim 35, wherein the sustained release carrier causes said opioid agonist to be released over a time period of about 24 hours when orally administered to a human patient.

Claim 39. (Currently Amended) The ~~oral dosage form of claim 19~~ method of claim 37, wherein the sustained release carrier causes said opioid antagonist to be released over a time period of about 12 hours when orally administered to a human patient.

Claim 40. (Currently Amended) The ~~oral dosage form of claim 19~~ method of claim 38, wherein the sustained release carrier causes said opioid antagonist to be released over a time period of about 24 hours when orally administered to a human patient.

Claim 41. (Currently Amended) An oral dosage form, comprising ~~active agents consisting essentially of~~ an orally therapeutically effective amount of

- (A) ~~at least one~~ an opioid agonist ~~selected from the group consisting of morphine, hydromorphone, hydrocodone, oxycodone, codeine, levorphanol, meperidine, methadone, oxymorphone, dihydrocodeine and pharmaceutically acceptable salts thereof,~~
- (B) acetaminophen, and

(C) ~~at least one~~ an opioid antagonist; the dosage form having a ratio of opioid antagonist to opioid agonist to acetaminophen that provides a combination product which is analgesically effective when the combination is administered orally, but which (i) is aversive in physically dependent human subjects when administered in the same amount as said therapeutically effective amount; and (ii) maintains an analgesic effect but does not increase analgesic efficacy of the opioid agonist together with the acetaminophen relative to the same therapeutic amount of opioid analgesic together with the acetaminophen when administered to human patients without said opioid antagonist.

Claim 42 (New) The oral dosage form of claim 1, wherein the antagonist included in the oral dosage form causes an aversive experience in a physically dependent addict taking about 2 to 3 time said therapeutically effective amount.

Claim 43 (New) The oral dosage form of claim 1, further comprising one or more pharmaceutically acceptable inert excipients.

Claim 44 (New) The oral dosage form of claim 1, further comprising an additional non-opioid drug selected from the group consisting of an NSAID, an NMDA receptor antagonist, a drug that

blocks a major intracellular consequence of NMDA-receptor activation, dimenhydrinate or a pharmaceutically acceptable salt thereof, and antitussive, an expectorant, a decongestant, and antihistamine, and mixtures thereof.

Claim 45 (New) A method of treating pain, comprising administering an oral dosage form according to claim 41 orally to a human patient in an analgesically effective amount.